REMARKS

Status of the Claims

Claims 43-50, 52, and 54-75 stand pending. Claims 51 and 53 were previously cancelled. Claims 62-71 and 74-75 have been previously withdrawn.

Claims 43-50, 52, 54-61 and 72-73 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent Publication No. 2004/0039452 A1 to Bessler in view of U.S. Patent No. 6,113,609 to Adams. Claims 43-50, 52, 54-61 and 72-73 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent Publication No. 2004/0082963 A1 to Gannoe in view of Adams.

Rejections under 35 U.S.C. § 103(a)

Bessler in view of Adams

Claims 43-50, 52, 54-61 and 72-73 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bessler in view of Adams.

The Examiner has not made a *Prima Facie* Case of Obviousness

As stated in the M.P.E.P. § 2142, in order to establish a prima facie case of obviousness, the references when combined must teach or suggest all of the claim limitations. The Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. M.P.E.P. § 2142. Applicants respectfully disagree with the rejection, and submit that the Examiner has not made a prima facie case of obviousness because even when the references are combined, the combination does not teach the invention as claimed.

Bessler discloses a gastric bypass stent 2 comprising a stent member 4 at the proximal end 6 of a tubular member 8 (paragraph [0018]). Adams discloses a system including an implantable fastener for fastening layers of tissue, including a proximal anchor member and a distal anchor member each being movable from a reduce profile position to a deployed position (Abstract).

Bessler fails to teach or suggest using at least one tissue anchor configured to have a transversely reduced configuration for passing transmurally through the attachment site and a transversely enlarged configuration after passing transmurally through the attachment site, to engage serosal tissue to retain the sleeve as claimed. Adams fails to make up for this deficiency.

Adams discloses methods and devices for treating gastroesophageal reflux disease, such as an implantable fastener that "includes a proximal anchor member and a distal anchor member each being movable from a reduced profile position to a deployed position" (Abstract). The fastener disclosed in Adams is used to fasten tissue layers together by creating a mucosal to mucosal tissue plication between the esophageal wall and gastric wall (Figs. 12-14, 17-20). As shown, for example, in Figure 14 of Adams, in order to form a tissue plication as disclosed, the tissue fastener must be delivered endoscopically such that one end of the fastener engages the mucosal wall of the esophagus (e.g., at 20c, Fig. 14) and the other end of the fastener engages the mucosal wall of the stomach (e.g., at 30c, Fig. 14). This allows the fasteners to be implanted to secure the stomach S to the lower esophagus E such that the stomach S applies a compressive force to the esophagus E that tends to reduce the inner luminal diameter of the esophagus E, reducing the likelihood of the stomach contents being able to pass through the esophagus E (col. 9, lines 55-65).

Thus, combining Bessler with Adams would result in a gastric bypass stent wherein an end of the tissue fastener would necessarily engage mucosal tissue, in contrast to serosal tissue as claimed, because the serosal tissue layers would be located in the center of the plication, and could not engage a tissue anchor for the purpose of retaining the sleeve. As the combination of references fails to teach or suggest each and every claim element, the Examiner has not made a prima facie case of obviousness. Thus, Applicants request that the rejection be withdrawn.

One of Ordinary Skill Would Have No Reason to Combine the References

In the Court's recent decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. _____ (2007), the Court repeatedly emphasized the value of determining if there is any "reason to combine" the various teachings in the art. The Court noted that "[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art." (*KSR*, Syllabus, page 4 and page 14).[1] Thus, the Court has made it

[1] The Court also noted that "it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does." (KSR, Syllabus, page 5; see also, page 15). Additionally, the Court noted that "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, page 15).

abundantly clear that some reason to combine the various elements must be present in order to establish a *prima facie* case of obviousness.

Applicants respectfully submit that one of skill in the art would have absolutely no reason to add transmural attachment anchors which are movable from a reduced cross section to an enlarged cross section to the disclosure of Bessler. To the contrary, Bessler teaches a nonpuncturing attachment system, in the form of a self expandable or balloon expandable stent. Even assuming arguendo that one would add a tissue fastener as described in Adams to Bessler's stent, there would be no reason to attach it such that it engages serosal tissue to the sleeve. As stated in Applicant's disclosure, serosal tissue in contact with itself when creating a plication (as shown in Fig. 14 of Adams), with both ends of a tissue fastener engaging mucosal tissue tends to heal together to form a seal (paragraph [0358] of the present application). This fusion of two serosal layers together will cause an irreversible change to a patient's anatomy. The pinching of the wall of the stomach brings serosa into contact with itself across the fold, which is known to promote serosa to serosa tissue healing, thereby making the plication permanent.

In contrast, when a tissue anchor engages serosal tissue to the sleeve as claimed (and as illustrated in Fig. 46B of Applicant's disclosure), the anchor can advantageously be removed at a later date without changing the patient's anatomy as unlike the plication created by Adams's fastener, two serosal layers do not come in direct contact which each other.

Secondary Factors Support A Finding of Non-Obviousness

Secondary considerations must be considered in every case where they are presented. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983); *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007). These include factors such as unexpected results, long-felt need, and failure of others. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986); *Graham v. John Deere*, 383 U.S. 1 (1966); *In re Sullivan*, No. 2006-1507 (Fed. Cir. 2007)(holding the PTO is obligated to consider applicant evidence of secondary consideration in cases where obviousness is at issue). A *prima facie* case of obviousness can also be rebutted if the applicant can show that the art in any material respect taught away from the claimed invention. *In re Haruna*, 249 F.3d 1327 (Fed. Cir. 2001).

Unexpected Results

Unexpected results can rebut a *prima facie* case of obviousness because that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious. *In re Soni*, 54 F.3d 746 (Fed. Cir. 1995).

Applicants submit that attaching the tissue anchor to engage serosal tissue to retain the sleeve as claimed advantageously and unexpectedly allows for a secure attachment of the sleeve with a decreased risk of migration, while still allowing for the tissue anchor to be withdrawn at a later date, without causing an irreversible change to a patient's anatomy caused by a tissue plication, as disclosed in Adams as well as Gannoe (discussed below). Such unexpected advantages have been disclosed in Applicants' co-pending application published as U.S. Pub. No. 2007/0198074 A1, paragraphs [0141] to [0143] reproduced below (with figure and reference numbers referring to the respective figures of that publication):

> [0141] Without being limited to any particular structure or mechanism, Applicants believe that the presence of the attachment device as claimed may cause or accelerate the formation of a layer 186 of serosal tissue having increased tissue density relative to unaffected or normal serosal tissue. The layer of increased density 186 may result from a process in which the transverse retention surface 182 places pressure against the serosa 170, causing a localized necrosis due to the restriction of capillary blood flow. The necrosed tissue thereafter fibroses, as a part of a normal healing response. The layer of increased density 186 or fibrosis may also result from a foreign body reaction triggered by the presence of the transverse retention surface 182. Applicants have observed a greater degree of fibrosis or denser tissue on the side of the T-tag facing the lumen of the stomach, for example on the retention surface 182.
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> [0142] In certain animal trials conducted by Applicants in which the animals were sacrificed five weeks following implantation of the attachment device 178, successful anchors appeared similar to the simplified schematic illustration of FIG. 5C. In this illustration, the location of the retention element 180 has changed

relative to the serosa 170 and muscularis 172, and the distal surface 188 of the retention element 180 has been covered with an overgrowth of serosal tissue 190. A fibrotic layer 186 is positioned in between the retention surface 182 and the muscularis 172. Although illustrated only on the proximal side of the retention element 180 where the greatest degree of fibrosis has been found to occur, the fibrotic response appears to some extent to surround and wall off the entire retention element 180.

[0143] It appears to the present inventors that formation of a sufficient fibrotic response on the proximal side of the retention surface 182 decreases the likelihood that the attachment device 178 will relocate to the inside of the stomach under normal agitation of the stomach, changes in the thickness of the stomach wall, and other conditions normally occurring in the stomach.

In conclusion, results of Applicants' experiments engaging a serosal surface have shown a dramatic and unexpected difference over previous attachment methods where a fastener engages a mucosal surface of a plication, as taught by Adams and Gannoe.

Teaching Away

Furthermore, Bessler discloses that his device is advantageous as less traumatic than previous surgical techniques (paragraph [0005]). All disclosed embodiments of Bessler's device, involve an expandable stent 4 (Fig. 1) that does not penetrate any tissue walls to meet its objective of securing the ends of the device within the esophagus. In general, the teachings of Bessler would lead one of skill in the art in the direction of a non-penetrating anchoring system, such as a balloon expandable or self expanding stent as disclosed therein. Thus, Applicants submit that Bessler tends to teach away from use of a penetrating tissue attachment, and that use of Adams's penetrating tissue fastener to secure Bessler's bypass stent would be contrary to Bessler's intent to providing a less traumatic device for gastric bypass.

Gannoe in view of Adams

As noted above and stated in the M.P.E.P. § 2142, in order to establish a prima facie case of obviousness, the references when combined must teach or suggest all of the claim limitations. The Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. M.P.E.P. § 2142. Applicants respectfully disagree with the rejection, and submit that the Examiner has not made a prima facie case of obviousness because even when the references are combined, the combination does not teach the invention as claimed.

The Examiner has not made a *Prima Facie* Case of Obviousness

Gannoe discloses methods and devices for creating a tissue ring. As shown in Fig. 5E of Gannoe, use of the disclosed device results in acquiring tissue folds in a circumferential configuration within a hollow body organ (Abstract) with mucosal tissue on both external surfaces of the placation, and serosal tissue "sandwiched" in between the mucosal layers. This results in each end of the staple being attached to a mucosal surface of tissue. Attachment of a bypass conduit 113 at the GEJ at the tissue ring, as shown in Fig. 5E of Gannoe, results in each end of the staple engaged within mucosal tissue of a circumferential tissue fold.

Likewise, as noted above, Adams' tissue fastener is used to create a multi-layer mucosal to mucosal tissue plication, where each end of the fastener necessarily rests against mucosal tissue. Thus, combining Gannoe with Adams would result in a gastric bypass stent wherein both ends of the tissue fastener would engage mucosal tissue on the external surfaces of the plication, in contrast to serosal tissue as claimed. As noted above in regards to the combination of references fails to teach or suggest each and every claim element, the Examiner has not made a prima facie case of obviousness. Thus, Applicants request that the rejection be withdrawn.

One of Ordinary Skill Would Have No Reason to Combine the References

Even assuming arguendo the combination of Gannoe and Adams could be further modified to arrive at the claimed invention, Applicants submit that one of ordinary skill in the art would have no reason to do so, such that a tissue anchor engages serosal tissue to the sleeve. As noted above and shown in Figs. 5A-5E of Gannoe, Gannoe teaches a mucosal to mucosal puncture of a plication, for the purpose of both reducing the diameter of the opening at the base

of the esophagus and permit serosa to serosa healing to enable a lasting clinical result. This disclosure would not give one of ordinary skill in the art any reason to eliminate the plication which is contained in every embodiment disclosed in Gannoe, and instead use a simple transmural attachment anchor.

Furthermore, engaging serosal tissue to retain the sleeve as claimed would not result in the acquisition of a circumferential tissue fold and thus render Gannoe's device unsuitable for its purpose, and act as a disincentive to the combination proposed by the Examiner. *See Tec Air Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999)(if a proposed modification would render the prior art device being modified unsuitable for its intended purpose, the proposed modification would not have been obvious).

Secondary Factors Support A Finding of Non-Obviousness

Unexpected Results

As noted in the discussion of Bessler above, Applicants submit that attaching the tissue anchor to engage serosal tissue to retain the sleeve as claimed advantageously and unexpectedly allows for a secure attachment of the sleeve with a decreased risk of migration, while still allowing for the tissue anchor to be withdrawn at a later date. This does not cause an irreversible change to a patient's anatomy caused by a tissue plication, as necessarily results from both the disclosed methods of Gannoe and Adams. Such unexpected advantages have been disclosed in Applicants' co-pending application published as U.S. Pub. No. 2007/0198074 A1, paragraphs [0141] to [0143] and reproduced above.

Claim Objections

The Examiner objected to Claim 52, finding that the recitation of a "T-tag" is overly broad, indefinite, unclear, and fails to particularly point out what applicant considers his invention or any corresponding structure. Applicants disagree, and submit that a "T-tag" is both understood in the art, and is clearly defined in the disclosure.

For example, paragraph [0166], states in part that a "T-tag is basically a cross member or "T" that is attached to an elongated member or tail at or near the mid-point of the T." As recited

in paragraph [227], "the purpose of the T in a T-fastener is to distribute and resist the forces that could act to pull it through the tissue, in this case the gastric wall".

In general, the T-tag is one way of providing a serosal surface footprint which resists retraction through the stomach wall. The anchor passes transmurally from inside the tissue wall to outside the wall in a reduced cross-sectional configuration (*e.g.* by orienting the cross bar on the T into parallel with the axis of penetration) and enlarges (*e.g.* by inclining the cross bar on the T into parallel with the serosal surface) following deployment. As recited in paragraph [0166], "T-tag fasteners are generally configured to flex at the juncture of the T and tail to allow delivery along the axis of the T through a minimal puncture diameter."

Applicants respectfully request that this objection be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In light of the foregoing remarks, Applicants respectfully submit that the present application is in condition for allowance. If any matters should remain, the Examiner is invited to contact the undersigned at the telephone number provided below. Please charge any fees, including any fees for additional extensions of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 10/31/07

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